

## Remarks

In the June 7, 2006 final action of the United States Patent Office Examiner Hand rejected Applicant's claims 1 through 20 on 35 U.S.C. 102, 103 saying that the no language specifically setting forth the absence of supporting structure was in the claims. In addition the introducer is said to be a support that could be left in Examiner Hand's rejecting claims 17, 19, and 22. Negative limitations are in the independent claims submitted herewith thus removing any doubt that tubing or sheath is about the plurality of fibers or the introducer during drainage. Consequently, the fibers are free to shift and move accommodating the drainage and healing.

Applicant appreciates that the prior rejections of claims 1-7, 9, 11-15, and 17- 20 under 35 U.S.C. 102 has been withdrawn in view of arguments made. The undersigned attorney had a telephone interview with about proposed claims that clearly removed the tubing, sheath or introducer from the claimed drain in an effort to narrow the issues and understand the new grounds of rejection made by Examiner Hand in view of a different interpretation of United States Patent 6,605,068. Applicant's remarks and arguments herein specifically address the cited portions of '068 in connection with the submitted amended independent claims 1, 9 and 21.

Examiner Hand rejects Applicant's claims 1-3, 9-12, and 17-22 under 35 U.S.C. 102(e) as anticipated by '068 citing column 1, lines 64, 65 and column 2, lines 8, 9, 25-28 and stating that the strands are loose even though Figure 2 shows a tightly wound cord described as a shoelace column 1, lines 64 and 65. The cord is described in '068 as loosely inserted in the sheath implying axial movement and not the spreading accommodating movement disclosed and claimed by Applicant. The teachings of spreading in '068 appears in column 2, lines 25 to 28 wherein the spreading is only in the wound. Applicant's claim 9 has the step of accumulating the plurality of fibers loosely but that is not the same as something described as inserted loosely into a sheath and there is no sheath in Applicant's now claimed drain. Examiner Hand cites column 2, lines 12 to 14 of '068 wherein the sliding of the sheath is disclosed for removal of that drain and

cord enclosed in the sheath from the tissue. The '068 disclosure of a drainage cord in a sheath has no specific teachings of the methods of use or manufacture as claimed by Applicant. One need look no further than the figures of '068 to know that its disclosure is merely a specific structure including a sheath and is not what Examiner Hand says anticipates Applicant's apparatus or method claims as now amended. Applicant's amendments make the claims allowable and this rejection should be withdrawn.

For support for Applicant's amendments please see the portions of Applicant's application as filed reproduced below.

"Recent United States Patent 6,605,058 has a gravity drainage cord formed by braiding a plurality of strands of silk of the type used for surgical sutures, and fitted or assembled loosely, in the median region, in a tubular sheath made of a material such as silicone. The outer silicone tube facilitates sliding of the assembly with respect to tissue, increases biocompatibility and allows optional coupling to mechanical aspiration units. Capillary action is said to be the mechanism of drainage. The protrusion of the cord into the wound allows small movement and if more than one cord is used some distributing and spreading are taught to increase drainage. Inside the cavity to be drained the tube may have radial holes to facilitate drainage. **No use of the cords without the tube is acceptable and no mechanism other than capillary action is disclosed.** The disclosure of Patent 6,605,058 is incorporated by reference and made a part of this background." (Emphasis added)

From the application as filed the wound or surgical site or anatomical opening includes the exit through the patient's skin as shown and described in the application and as set forth in photographs and the inventors 132 affidavit and as now presented in the Applicant's amended claims. Also from the application as filed:

"The flexibility and adaptability of the plurality of fibers 12 also accommodated the form or shape of wound or surgical opening 16 that can take many contours as previously explained. The referenced prior patents and drainage devices do not have or perform the feature of spreading out within the wound or surgical site."

Applicant's 132 affidavit includes evidence that sheath less or tubeless drain flexible and loose fibers guide and direct flow along, among and about each

flexible fiber. That is how it performs and works without any support tubing or sheath and how it reduces trauma and speeds healing. That flexibility permits the fibers to spread out and collect the drainage internally and allows the rapid healing of the exit opening about the flexible fibers with minimal trauma. Data, test results, observations and insight on how the claimed drain functioned in experimental trials after surgery and why it performed better is in the 132 affidavit. Quantification of the merit of the flexible fiber drain is also provided. The clinical tests support the way in which the claimed drain performs and works and its resistance to clogging, faster healing, less trauma, etc. The '068 patent cited by Examiner Hand fails to teach the specifically claimed elements or method steps that are unique to the Applicant's claims.

Method claim 9 has the steps of:

“...providing a plurality of fibers each having an internal end, an external end and a middle there between, each fiber elongate with a thickness and a length wherein its thickness is substantially less than its length for flexibility;  
gathering the plurality of fibers together near their external ends;  
allowing the internal ends and middle to remain unrestrained for spreading within the wound or surgical site and anatomical opening;  
guiding bodily fluid along and amongst the fibers from the internal ends along the middle and percutaneously without any supporting sheath or tubing extending thereabout or surrounding the plurality of fibers and to the gathered together external ends during drainage of fluid from a wound or surgical site and anatomical opening;  
positioning an external collector cover over and in fluid communication with the gathered together external ends and covering the wound or surgical site and anatomical opening;  
accumulating bodily fluid in the external collector cover from plurality of fibers at their unrestrained internal ends which are inside the wound or surgical site and anatomical opening, and  
spreading divergently at least the internal ends for accumulating bodily fluid and for guiding bodily fluid along and amongst the fibers from the internal ends along the middle and percutaneously without any supporting sheath or tubing extending thereabout or surrounding the plurality of fibers and to anatomically fit percutaneously in or through the wound or surgical opening for drawing and guiding fluid from inside the wound or surgical site and anatomical opening to the gathered together external ends during drainage.”

Those steps were not suggested or disclosed '068 and thus Applicant's claimed method is new and unobvious.

Dependent claim 20 is rejected by Examiner Hand with the statement that '068 teaches the plurality of middle fibers in the middle are thus capable of flexing and shifting relative to one another so that the cross section thereof approximates the cross section of the percutaneous incision at the surgical site through which the plurality of middle fibers passes. Applicant does not agree with the Examiner's view of the '068 teachings and respectfully requests a citation in '068 whereat the specific teaching that appears to include Applicant's claim language can be found. Amended dependent claim 20 includes the lack of a supporting sheath or tube and depends from similar claims; there is always a sheath and a twisted cord in '068.

Claims 21 and 22 drawn to the method of manufacture are rejected as anticipated by '068. In particular, in '068 there is a sheath coupled to a mechanical aspiration unit that functions as an external collector. Amended independent claim 21 includes that which allows optional coupling to mechanical aspiration units. There is no manufacturing steps taught in the disclosure of an apparatus of sheath and cord in '068 and Applicant's method step of coupling is not shown or described such that there would have been anticipation. Applicant's method claims the loose bundle of fibers and no supporting structure particularly internally and in the middle. Applicant's claimed manufacturing steps are not like the teachings or the disclosure of the cited '068 reference.

The Applicant's claimed particulars on vacuum applied to drainage are dependent upon the flexible fibers without a sheath or tubing wherein the plurality of fibers passes through the tissue to the wound or exit opening for capture at the collector. Active and passive drainage is described by Applicant in the background of the application as filed and the rejected dependent claims 8 and 16 add the active aspiration to the claims from which they depend and which are allowable. Similarly, fibers that are bioabsorbable, antimicrobial, anticoagulant and/or anti-thrombogenic are not claimed by Applicant without including structure

or method steps in claims 5-7, 13-15 depend on claims that have no sheath, tubing or introducer.

In view of these amendments to the claims, arguments, remarks and the Examiner's finding that the previous arguments and affidavit are persuasive must apply to the amended claims. Rejections based on the sheath and cord in '068 are not relevant to Applicant's drain or methods of use and manufacture that are claimed with a lack of tubing, sheath or introducer surrounding the plurality of fibers internally or percutaneously in the tissue. All the dependent claims should be allowable. The claims have been amended, corrected and clarified. Should there be any questions, the Examiner is encouraged to call or email the Applicant's undersigned attorney.

Respectfully submitted on behalf of Applicant and for prompt allowance,

 9/6/06

Aaron Passman Registration Number 26,783  
9632 Windom Point Avenue  
Las Vegas, Nevada 89129  
(702) 341-9066  
apassman@cox.net